

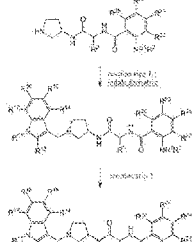
## DETAILED ACTION

**Status of the claims:** Claims 1-3, 7-36, and 53-57 are currently pending.

### *Election/Restriction*

Applicant elected the following group without traverse in the response dated 10/8/2008:

Group I, claim(s) 1-3, 7, 8, 32-36 drawn to a process for making a product characterized



***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 refers to “the indole derivative” apparently as a reactant without providing any description of the specific structure of the reactant. One of ordinary skill in the art knows what an indole is, however applicant’s meaning of “derivative” would not sufficiently describe the metes and bounds of the claim. Claims 1 and 8 refer to “reaction steps” without describing what the step entails. The claims describe associated conditions and what the step “involves” but never specifically claims the components of the step.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

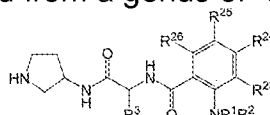
4. Claims 1-3, 7, 8, and 32-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are for a method of making a genus of compounds, one of

ordinary skill in the art would not be able to practice the entire scope of the invention based on the limited disclosure.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

*Nature of Invention.* The invention pertains to a method of making a genus of compounds using a genus of reactants *comprising* reaction steps 1 and 2.

*Scope of the Invention.* The scope of the invention is open ended as a result of the use of “comprising”; the reactants used are selected from a genus of “the indole derivative”,



three reagents and a compound of the formula . The reaction steps comprise “steps 1 and 2” without defining anything particular to the step. The method has 13 variable substituents each having more than 6 alternatives (approximately 6<sup>13</sup> or > 13 billion alternatives).

*State of the Art and Level of Skill in the Art.* Although the level of skill in the art is very high, one of ordinary skill in the art would not be able to predict whether a particular reaction would work as claimed given the vast possible variations of the method.

*Number of Working Examples and Guidance Provided by Applicant.* The applicant has provided no working examples. The specification only describes generic schemes without specificity to the process steps.

*Unpredictability of the Art and Amount of Experimentation.* The method claimed presumably uses a reaction which is unpredictable as discussed in the Katritzky references. The reaction taught by the prior art shows that the coupling could occur at positions other than those intended in the claims. In addition, other undesirable reactions may occur including, for example, rearrangement. Furthermore, there would be an undue amount of experimentation required to discover the actual conditions that facilitate the reaction steps in addition one of ordinary skill in the art could not predict whether the reaction would be successful for the scope of the claims. Thus there would be an undue burden on the skilled artisan to practice the entire scope of the invention.

Furthermore, the MPEP states in chapter 2100:

"... in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. In re Soll, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work."

Considering the above factors, the claims are not enabled for the entire scope claimed.

### ***Conclusion***

The claims are not in condition for allowance.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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